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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,825	11/18/2003	Gregory Stephanopoulos	MIN-P01-042	7074

28120 7590 12/16/2005

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EXAMINER

STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/716,825	STEPHANOPOULOS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amber D. Steele	1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-32 are currently pending.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11 are drawn to a method for diagnosing oral disease, classified in class 435, subclass 6.
  - II. Claims 12-26 are drawn to a business method for allowing a dentist to provide for detection of oral disease, classified in class 705, subclass 2.
  - III. Claims 27-30 are drawn to a diagnostic apparatus, classified in class 435, subclass DIG 45.
  - IV. Claims 31-32 are drawn to sample collection and delivery apparatus, classified in class 435, subclass 309.1.
3. The inventions are distinct, each from the other because of the following reasons:
  - A. Inventions I-II represent independent and/or patentably distinct methods. Groups I and II represent separate and patentably distinct methods because they use different steps, require different reagents and/or will produce different results. For example, Group II requires the method step of “notifying the patient the results of the test” and further comprises “requesting insurance reimbursement for the test”, which are not required by Group I. Thus, the search for Groups I and II would not be coextensive. In addition, the inventions of Groups I-II have separate status in the art as shown by their different classifications (see paragraph 2 above). Furthermore, it would be burdensome to search the inventions of Groups I-II together. Moreover,

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Groups I-II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

B. Inventions III-IV are drawn to independent and/or patentably distinct apparatuses since these apparatuses have different structures and/or different functions. For example, Group III requires a diagnostic “system” and a notification “system” which Group IV does not.

Therefore, Groups III-IV have different issues regarding patentability and enablement.

Additionally, Groups III-IV represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group III would not necessarily anticipate or render obvious Group IV or *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups III-IV have a separate status in the art as shown by the different classification (e.g. subclass; please refer to paragraph 2).

C. Inventions I-II and III-IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced “by hand” with common laboratory equipment including a cotton swab, pipettes, thermocycler, gel box and power supply, light box, camera and film, a computer, and a telephone. Furthermore, Groups I-II (distinct methods) and III-IV (distinct apparatuses) have been shown to be patentably distinct inventions (please refer to sections 2A-B above).

4. Because these inventions are distinct for the reasons given above and:

- a. have acquired a separate status in the art as shown by their different classification (please refer to section 2), and/or
- b. divergent subject matter which would require different bibliographic and/or classification searches; and/or
- c. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Species Election***

5. This application contains claims directed to the following patentably distinct species of the claimed inventions for Groups I-II. Election is required as follows.

6. If applicant elects the invention of **Group I**, the applicant is required to elect a single, specific species from **each** of the following species A-E.

A. species of expression level (see claims 2 and 5)

Applicant must elect, for the purposes of search, a **single, specific species** of expression level.

B. species of method of determining (see claims 4 and 7)

Applicant must elect, for the purposes of search, a **single, specific species** of method of determining.

C. species of gene

Applicant must elect, for the purposes of search, a **single, specific species** of gene.

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D. species of biological sample

Applicant must elect, for the purposes of search, a **single, specific species** of biological sample.

E. species of oral disease

Applicant must elect, for the purposes of search, a **single, specific species** of oral disease.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112, first paragraph.

7. If applicant elects the invention of **Group II**, the applicant is required to elect a single, specific species from **each** of the following species A-E.

A. species of expression level (see claims 13 and 15)

Applicant must elect, for the purposes of search, a **single, specific species** of expression level.

B. species of method of determining (see claim 17)

Applicant must elect, for the purposes of search, a **single, specific species** of method of determining.

C. species of gene

Applicant must elect, for the purposes of search, a **single, specific species** of gene.

D. species of biological sample

Applicant must elect, for the purposes of search, a **single, specific species** of biological sample.

E. species of oral disease

Applicant must elect, for the purposes of search, a **single, specific species** of oral disease.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112, first paragraph.

8. Applicant is advised that a reply to this requirement must include **an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicant to request an oral election was not made. See MPEP § 812.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Future Correspondences***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:00 PM.



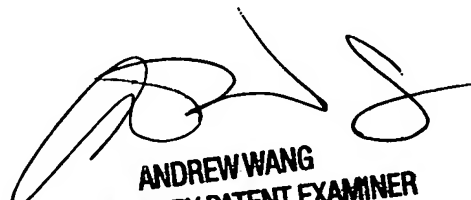
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS

November 23, 2005



ANDREW WANG  
SUPERVISORY PATENT EXAMINER  
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